UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

A.O.A., *et al*.,	)	
	)	Case No. 4:11-cv-00044-CDP
Plaintiffs,	)	(CONSOLIDATED)
	)	
vs.	)	
	)	
THE DOE RUN RESOURCES CORPORATION, *et al*.,	)	
	)	
	)	
Defendants.	)	

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE OR LIMIT THE PROFFERED OPINION TESTIMONY OF PLAINTIFFS' EXPERT WITNESS DR. DAVID C. BELLINGER UNDER RULE 702 AND *DAUBERT*

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

I. INTRODUCTION

Dr. David Bellinger is a well-recognized neuropsychologist and epidemiologist who has published numerous academic papers on the potential effects that exposures to lead and, to a lesser extent, arsenic,[1] can have on neurodevelopment.

Here, Dr. Bellinger intends to offer opinion testimony that Plaintiffs' injuries as diagnosed by Karen Hopkins, M.D. and Clemente Vega, Psy.D. are "consistent with" effects of lead and arsenic exposure documented in the scientific literature. Specifically, Dr. Bellinger opines that the levels of lead and arsenic to which Plaintiffs have allegedly been exposed are associated with decreases in IQ and behavioral issues including attention deficit hyperactivity disorder ("ADHD") and aggression. *See* Ex. A, Expert Report of David Bellinger ("Bellinger Rep."), at 14-16; Ex. B, Deposition of Dr. Bellinger ("Bellinger Dep.") at 26:13-19. In reaching these opinions, however, Dr. Bellinger failed to consider significant confounders and to discuss the extremely low impact lead and arsenic exposure have been found to have on the health endpoints at issue when compared to other risk factors (*see* Ex. C, Expert Report of Barbara D. Beck ("Beck Rep.") at 27), despite consistently acknowledging the significance of these factors in his published academic work.

Dr. Bellinger's opinion testimony should be excluded or limited under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms.*, Inc., 509 U.S. 579 (1993), and its progeny for three reasons. **First**, Dr. Bellinger's opinions that lead and arsenic exposure can cause various neurological, behavioral, and other health effects is the product of a methodology that is inconsistent with his scientific work outside the courtroom: he fails to account for or rule out other factors that can

[1] As discussed in Defendants' Motion for Summary Judgment, filed concurrently herewith, Plaintiffs' claims based on their alleged exposures to arsenic fail as a matter of law because they have not come forward with expert evidence showing that those exposures caused any of their injuries.

impact IQ and behavioral conditions more significantly than lead or arsenic exposure. **Second**, to the extent Dr. Bellinger expresses specific causation opinions, those opinions should be excluded. He is not a medical doctor and not qualified to render such opinions and he failed to follow the steps necessary to render such opinions. **Third**, to the extent Dr. Bellinger attempts to testify regarding the alleged carcinogenicity of arsenic, he should not be permitted to do so because he conceded at deposition that he has no opinions on this issue. Further, no Plaintiff alleges that they have cancer or a pre-cancerous condition, so this opinion fails the *Daubert* relevance or "fit" requirement. These opinions are also unnecessarily cumulative of Dr. Jill Ryer-Powder's proposed testimony.

Defendants respectfully request that the Court exclude or limit Dr. Bellinger's testimony regarding the alleged neurodevelopmental impacts of lead and arsenic exposure, specific causation, and the alleged cancer risks of arsenic.

II. LEGAL STANDARD

Under *Daubert* and Federal Rule of Evidence 702, a federal district court has a ***duty*** to act as a "gatekeeper," ensuring that only scientifically reliable and relevant expert evidence is presented to the jury. *Daubert*, 509 U.S. at 589. Rule 702 provides that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if":

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

In *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 561 (8th Cir. 2014), the court

explained that "[t]he screening requirement of Rule 702 has been boiled down to a three-part test":

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Id. at 561. "The proponent of the expert testimony must prove its admissibility by a preponderance of the evidence." *Redd v. Depuy Orthopaedics*, 700 F. App'x 551, 554 (8th Cir. 2017).

"To show that the expert testimony is relevant, the proponent must show that the reasoning or methodology in question is applied properly to the facts in issue." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006); *see also Daubert*, 509 U.S. at 591-92 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."); *Lauzon v. Senco Prods., Inc*., 270 F.3d 681, 687 (8th Cir. 2001) (court must consider "whether the proposed expert sufficiently connected the proposed testimony with the facts of the case"). "Failure to show the reliability of each step in an expert's methodology is fatal under *Daubert*." *In re Baycol Prod. Litig*., 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007). Moreover, "[e]xpert testimony that is speculative is not competent proof and contributes nothing to a legally sufficient evidentiary basis." *J.B. Hunt Transp., Inc. v. GMC*, 243 F.3d 441, 444 (8th Cir. 2001).

In *Daubert*, "the Supreme Court set forth four factors to guide district courts in resolving admissibility questions: whether the expert's methodology has been tested, has been subjected to peer review, has a known or knowable error rate, and is generally accepted in the scientific community." *Kirk v. Schaeffler Grp. USA, Inc*., 887 F.3d 376, 391 (8th Cir. 2018). "*Daubert*'s progeny provides additional factors such as: whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative

explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Lauzon*, 270 F.3d at 687. In weighing these factors, the court properly exercises its gatekeeping function by "separat[ing] expert opinion evidence based on 'good grounds' from subjective speculation that masquerades as scientific knowledge." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001). Under this standard, the Court should exclude or limit Dr. Bellinger's proposed expert testimony.

III. PLAINTIFFS HAVE FAILED TO MEET THEIR BURDEN UNDER *DAUBERT* AND RULE 702 TO SHOW THAT DR. BELLINGER'S TESTIMONY IS RELIABLE AND RELEVANT TO THE FACTS OF THIS CASE

A. Dr. Bellinger's Opinions Do Not Follow the Methodology He Uses in his Scientific Work and Are Thus Unreliable and Inadmissible

Dr. Bellinger purports to provide general causation testimony for Plaintiffs regarding the alleged relationship between lead and arsenic exposure and various neurological, behavioral, and other health effects. "General causation is a showing that the drug or chemical is capable of causing the type of harm from which the plaintiff suffers." *See In re NuvaRing Prods. Liab. Litig.*, No. 4:08-MD-1964 RWS, 2013 WL 12435800, at *5 n.4 (E.D. Mo. Apr. 10, 2013) (citing *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 450 (8th Cir. 2010)).

To establish reliability under *Daubert*, a court is required "to satisfy [itself] that the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting." *See Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997); *FURminator, Inc. v. Kim Laube & Co.*, 758 F. Supp. 2d 797, 808 (E.D. Mo. 2010); *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563, 622 (S.D. Tex. 2005) ("in making the reliability inquiry, it is the district court's responsibility 'to make certain that an expert … employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field'") (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). Accordingly, the

Daubert standard is meant to limit the "abuse [of] hiring of reputable scientists, impressively credentialed, to testify for a fee to propositions that they have not arrived at through the methods that they use when they are doing their regular professional work rather than being paid to give an opinion helpful to one side in a lawsuit." *Braun v. Lorillard Inc.*, 84 F.3d 230, 235 (7th Cir. 1996). In addition, courts must consider "[w]hether the expert has adequately accounted for obvious alternative explanations" when assessing the reliability of an expert's methodology. Fed. R. Evid. 702 Adv. Comm. note (citing *Claar v. Burlington N.R.R.*, 29 F.3d 499, 502 (9th Cir. 1994)); *see also Lauzon*, 270 F.3d at 687.

Dr. Bellinger has published many papers regarding lead's (and to a lesser extent arsenic's) potential effects on neurocognition. The methodology he employs in his academic pursuits is therefore well established. The methodology he used in arriving at his opinions for this case, however, differs drastically from that employed in his academic work. Specifically, Dr. Bellinger fails to account for or rule out confounders that he has repeatedly acknowledged are significant to the analysis of endpoints like IQ and behavioral effects such as ADHD. He, as a result, overstates the strength of the evidence supporting his opinions in a manner that is inconsistent with his academic work.

1. Dr. Bellinger failed to consider factors that he has deemed to have significant impacts on IQ in his academic work

In his academic work, Dr. Bellinger repeatedly emphasizes the importance of accounting for factors that impact IQ to a greater extent than lead exposure. These include genetics, poverty, home environment, and nutrition, among others. In this case, however, he has failed to account for any of those factors, stating instead – without support – that at the "high levels" at issue in this case, the confounding factors "will be less important." *See* Ex. B, Bellinger Dep. at 55:6-9.

But in his published papers, Dr. Bellinger makes clear that ***IQ is influenced by many***

factors. For example, he has written that:

- "The first lesson is that neurodevelopment is a complex outcome that is influenced by many factors other than metal exposures."[2]
- Even in cases of proven exposures to lead, "it is likely that the form in which neurodevelopmental toxicity is expressed depends on factors such as age at exposure, coexposures to other neurotoxicants, nutritional status, genotype and the characteristics of the home environment."[3]
- "Increased exposure to lead frequently occurs in the context of other factors that also place a child at increased neurodevelopmental risk (e.g., poverty, single-parent household, teen-age mother, child abuse, poor nutrition)."[4]

Indeed, when considering these other well-known confounders, Dr. Bellinger has found that "***children's BLLs tend to account for a relatively small amount of the variance in their neurodevelopmental status***" and that, instead, "***[o]ther factors, particularly social class and parental intelligence, typically account for much larger percentages of outcome variance.***"[5] In other words, because of the influence of well-accepted factors, elevation of blood lead levels "should be viewed as a risk factor for neurodevelopmental problems, ***not a diagnosis***."[6]

Dr. Bellinger acknowledges the significance of these confounders, admitting that "neurodevelopment is a complex outcome that is influenced by many factors." Ex. B, Bellinger Dep. at 63:17–19. He conceded that "among the most important" of these factors were "nutrition," "family dynamics," "how stimulating a child's environment is, opportunities for peer

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[2] Ex. D, D Bellinger, *Inorganic Arsenic Exposure and Children's Neurodevelopment: A Review of the Evidence*, 1 TOXICS 2, 11–12 (Oct. 2013) (hereafter "*Arsenic*").

[3] Ex. E, D Bellinger, *Very Low Lead Exposures and Children's Neurodevelopment*, 20 CURR. OPIN. PEDIATR. 172, 173 (2008) (hereafter "*Low Lead Exposures*").

[4] Ex. F, D Bellinger & Rappaport, *Developmental Assessment and Interventions*, in MANAGING ELEVATED BLOOD LEAD LEVELS AMONG YOUNG CHILDREN 79, 83 (Harvey, ed., 2002).

[5] *Id.* (emphasis added).

[6] *Id.* (emphasis added).

relationships," "quality of schools," "[g]enetics," and "[p]arental IQ." *Id.* at 64:3–10. He further agreed that "maternal education [and] IQ" and Home Observation Measurement of the Environment ("HOME") scores assessing how stimulating the home environment is are among "the major confounders" that are "really critical" and "typically used" in studies assessing the neurodevelopmental impacts of substances such as lead and arsenic. *Id.* at 51:4–52:2.[7]

Nonetheless, Dr. Bellinger has failed in this case to consider the effect of these other significant factors. Nowhere in his report does Dr. Bellinger discuss the potential impacts of Plaintiffs' socioeconomic conditions, parental IQs, genetics, educational access, exposure to smoking, or home environments on Plaintiffs' neurodevelopmental outcomes, even though it is undisputed that children in La Oroya face many of these very challenges, including poverty and malnutrition.[8] In fact, Dr. Bellinger fails even to discuss these factors as relevant to neurodevelopment generally or as to the residents of La Oroya more specifically.

This failure to consider significant confounders is especially problematic given that lead has no signature effect, combined with the nonspecific nature of Plaintiffs' claimed injuries. *See* Ex. E, *Low Lead Exposures* at 173 ("No single neurodevelopmental finding unequivocally

[7] The impacts of these factors are also explained by Dr. Barbara Beck, who notes in her report that "[r]isk factors associated with the cognitive endpoints of interest (in particular, intelligence) include genetics, socioeconomic status (SES), and environmental tobacco smoke (ETS)." Ex. C, Beck Rep. at 12. Just as Dr. Bellinger has stated in his academic work, Dr. Beck explained that "these factors typically have a greater impact on and account for much more variability in cognitive effects and behavioral impairments than [lead]." *Id.* (citing multiple studies); Ex. G, Deposition of Barbara Beck at 12:21 ("[T]he scientific literature does not allow you to draw conclusions regarding causality of lead, and specifically neurobehaviorality and cognitive effects in children or adults because … of the relative importance of the association of lead to those health endpoints versus other factors that are much more determinative of those health endpoints.").

[8] *See* Ex. H, Integral, *Human Health Risk Assessment Report* at 20 (2005) ("The Union for Sustainable Development (UNES) (1999) reports developmental deficiencies in children of La Oroya based on standardized testing, but notes that the cause is malnutrition, and other factors related to the socioeconomic status of area residents.").

identifies a child as having an elevated blood lead level, nor does there appear to be a group of findings, that in aggregate, define a 'signature' injury"); *see also* Ex. B, Bellinger Dep. at 37:17-19, 40:19-41:6 (agreeing abdominal discomfort, fatigue, headache, and constipation are "nonspecific symptom[s]" with "many causes"). Thus, there is no way to definitively attribute a neurodevelopmental outcome or health effect to lead exposure without accounting for or ruling out the many factors that are more likely to cause that outcome. This problem is further exacerbated by the fact that several Plaintiffs do not have any actual blood lead level measurements.[9]

When asked to explain why he did not consider the other well-known confounders in arriving at his opinions, Dr. Bellinger made the unfounded claim that confounders do not matter when the blood lead levels are high. *See* Ex. B, Bellinger Dep. at 54:18-55:15. When asked for the basis of this claim, Dr. Bellinger said he relied on his own experience with lead, but he failed to provide any explanation as to how this experience could support his opinion. *Id.* at 55:16–24. This statement is pure *ipse dixit* and not permitted under *Daubert* and its progeny. *Dreyer v. Ryder Auto. Carrier Grp., Inc.*, 367 F. Supp. 2d 413, 417 (W.D.N.Y. 2005) (An expert's "failure to explain why his training and experience led him to his conclusion is the reason why his opinion cannot be accepted. Without explaining the reasoning behind his conclusion, … the Court is left with the mere *ipse dixit,* or say so, of the expert."); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997) ("Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

[9] Dr. Bellinger acknowledged that some Plaintiffs did not have blood lead results but said he could assume their blood lead levels were "similar" based on the fact they lived in the same community. Ex. B, Bellinger Dep. at 120:23-121:16. This opinion is contrary to the scientific consensus, the authoritative literature on lead exposure, and even the opinion of Plaintiffs' expert David MacIntosh, who conceded that there is a great degree of variability in blood lead levels even at the same exposure levels and locations. *See, e.g.,* Ex. I, MacIntosh Report Fig. 9-4.

Moreover, this opinion is contrary to Dr. Bellinger's academic work. Dr. Bellinger has previously written that the relationship between lead exposure and IQ deficits is log-linear, meaning that much of the IQ loss associated with lead exposure occurs at lower blood lead levels, such that higher exposure levels do not result in significant additional damage. *See* Ex. E, *Low Lead Exposures* at 173 ("Not only do many studies support the existence of adverse effects below 10 µg/dl, but the rate of decline in IQ scores might be greater at blood lead levels below 10 µg/dl than it is at levels above 10 µg/dl."). Dr. Bellinger has previously opined that the steepest declines in IQ attributable to lead occur at BLLs between 1 and 10 µg/dl. *Id.* ("Two-thirds of this decline (6.2 points) was predicted to occur in the range of less than 1-9.9 µg"). By contrast, he found that, on average, an additional decline of only about one point can be attributed to a BLL between 20 and 30 µg/dl. *Id*.

Dr. Bellinger has failed to consider the numerous other potential alternative causes for Plaintiffs' alleged loss of IQ, despite acknowledging in his own academic work that these factors account for a significantly greater impact on IQ than lead exposure. Dr. Bellinger's methodology in support of his opinion that Plaintiffs' alleged IQ loss has been caused by lead exposure exclusively is litigation-driven, biased, and unreliable and should be excluded.

2. Dr. Bellinger's opinion about the alleged association between behavioral issues and lead exposure is inadmissible

Dr. Bellinger opines that in addition to IQ deficits, Plaintiffs have experienced other neurodevelopmental and behavioral impacts due to lead exposure, including ADHD and an increased propensity to aggression and violence. These opinions are litigation driven, contrary to his prior academic work, and inherently unreliable.

a. Dr. Bellinger fails to consider significant confounders

Dr. Bellinger recognizes that behavioral effects such as ADHD and a propensity for

violence, like IQ, are complex outcomes influenced by multiple factors. Ex. B, Bellinger Dep. at 63:14-23; 72:19-22. The clear consensus in the relevant scientific literature is that this is true. For example, in a study Dr. Bellinger cites in his report, the authors concluded that the results of their meta-analysis showed only a small association between BLLs and ADHD symptoms and that they could not reach "strong causal conclusions."[10] They further found that the "effect size" of lead's association with both inattention and hyperactivity/impulsivity "were in the small to moderate range, suggesting that lead exposure is associated with ADHD symptoms but is neither necessary nor sufficient for the development of the disorder." Ex. C, Beck Rep. at 21. Indeed, "genetics are considered to account for approximately 75 to 95% of ADHD etiology[.]" *Id*.

Similarly, in Wright (2008),[11] which Dr. Bellinger described as "the most persuasive evidence in the epidemiological literature" in support of a causal relationship between lead and aggressive behavior because it "collected information on a very wide range of potential confounders" (Bellinger Dep. at 70:24-71:1, 72:19-25), the authors stated that their study was limited by the presence of a number of confounders that they failed to or could not account for, including likely undercounting of actual criminal behavior amongst the cohort and significant limitations in their ability to account for socioeconomic status as a confounder. In addition, the authors explained that "[a]s pointed out by Weiss and Bellinger [] in their discussion of the social ecology of exposure to environmental pollutants, neurotoxicant exposures are not randomly distributed, but are 'chained' to many other risks to normal development that are sometimes quite difficult to partition." Ex. J at 737-38. Moreover, most of the relevant literature concludes there is

[10] Ex. J, Goodlad et al., *Lead and Attention Deficit/Hyperactivity Disorder (ADHD) Symptoms: A Meta-Analysis*, 33(3) CLIN. PSYCHOL. REV. 417, 423 (2013); *see also* Ex. C, Beck Rep. at 30.

[11] Ex. K, J Wright et al., *Association of Prenatal and Childhood Blood Lead Concentrations with Criminal Arrests in Early Adulthood*, 5(5) PLOS MED. 733, 737 (2008).

either no or only a very weak association between lead and aggression. Beck Rep. at 26.

Dr. Bellinger has cherry-picked data and ignored other scientific evidence suggesting that an individual's BLL is not, in fact, a significant driver of ADHD. As Dr. Bellinger acknowledged in his deposition, occurrence rates of ADHD have increased in the past two decades. Bellinger Dep. at 61:20-23. However, average BLLs have dropped significantly worldwide during that same time period. Beck Rep. at ES-1. If a strong association between ADHD occurrence rates and BLLs did exist, one would expect those levels to rise and fall together. In addition, Dr. Bellinger ignores significant recent scholarship analyzing past studies on the relationship between lead and aggression which shows that when socioeconomic status is more robustly accounted for, there is no association between lead and delinquent behavior. *Id*. at 25.

Despite acknowledging that, as with IQ, several factors other than lead exposure are more strongly linked to behavioral issues, including many of the same factors discussed in relation to IQ (Bellinger Dep. at 63:24-64:10), Dr. Bellinger fails to discuss entirely how those factors might have impacted Plaintiffs or how these factors are causally linked to behavioral effects. Thus, Dr. Bellinger's opinions regarding behavioral impacts are unreliable and inadmissible.

b. Dr. Bellinger's opinions relating to alleged behavioral effects are not based on proper scientific methodology

While "[e]vidence of an association may be sufficient for formulation of a hypothesis that can later be tested and confirmed, … it is not proof of causation in the courtroom or the scientific community." *See Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 969 (W.D. Mo. 2000). There is no way to determine that lead exposure has caused an individual to develop ADHD because there is no known causative mechanism for lead-associated ADHD or, in fact, any clear causation mechanism for ADHD in general. As Dr. Bellinger conceded in his deposition, the physiological differences associated with ADHD are not "really well understood at this point,"

and, further, "ADHD might be a number of different disorders." Ex. B, Bellinger Dep. at 62:20–63:10. In addition, while some imaging studies have identified possible differences between the brains of children with and without ADHD, none of the Plaintiffs have undergone the kind of brain imaging required to identify these differences. *Id.* Thus, while Dr. Bellinger offers arguments that lead is *associated* with ADHD, he has not and cannot offer any evidence that lead exposure *causes* ADHD, as required to prove general causation. The same is true of his causation opinions regarding aggression and violence.

Dr. Bellinger cites to several studies to support his opinions regarding the alleged association between lead and ADHD or lead and aggression. However, the four studies upon which he relies primarily are not generally accepted in the relevant scientific community. Specifically, in its comprehensive review of the lead literature, the U.S. E.P.A. found that these studies are not reliable "because of the cross-sectional or case-control design of the studies and inconsistent consideration for potential confounding by factors such as [socioeconomic status], parental education, or parental caregiving quality." E.P.A., *Integrated Science Assessment for Lead* (2013) at 4-289–90.[12] The studies he relies upon for his aggression opinions include similarly weak cross-sectional and case-control studies as well as ecologic studies, which Dr. Bellinger himself described as "the weakest for of epidemiological evidence." Ex. B, Bellinger Dep. at 72:15-18.

First, the studies that Dr. Bellinger cites cannot be used to establish causation. As discussed above, association is not sufficient to establish causation either in a court of law or within the scientific community. *Nelson*, 92 F. Supp. 2d at 969. None of the four primary studies Dr. Bellinger relies upon in his discussion of ADHD—Braun (2006), Froehlich (2009), Nigg (2008), and Nigg

[12] Available at https://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=518908 (hereafter "EPA ISA").

(2010)—can support a causation opinion. Most significantly, these studies did not establish whether the subjects were exposed to lead before or after they were diagnosed with ADHD or began experiencing symptoms of ADHD and, thus, cannot establish causation.[13] Similarly, the ecological studies (Nevin (2000) and Nevin (2007)) provide only population-level analyses, which make it impossible to determine "whether individuals with a specific disease in a given group were actually exposed and, if so, what their exposure level was." Ex. C, Beck Rep. at 26 n.41.

Second, these studies fail to account consistently for a variety of vital confounders.[14] For example, the authors of Braun (2006)[15] acknowledged that a significant weakness in their study was the "lack of consideration of confounders, such as prenatal alcohol exposure and parental psychopathology." Ex. C, Beck Rep. at 22 (explaining that Nigg (2008) adjusted only for sex and household income and Nigg (2010) adjusted only for maternal IQ and prenatal smoking exposure). EPA also noted that the studies generally did not consider HOME scores. *See* EPA ISA at 4-184; *see also* Ex. C, Beck Rep. at 20 ("As with cognitive effects, other risks factors (e.g., genetics, quality of the home environment, and SES) often are more strongly related to the behavior of interest than [lead]"). Nor did the studies account for family history of ADHD even though ADHD is "considered to have a strong familial component." EPA ISA at 4-151; Ex. C, Beck Rep. at 21 ("[G]enetics are considered to account for approximately 75 to 95% of ADHD etiology" (citing several studies)). This weakness is particularly significant because consideration of these

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[13] *See* Fedak et al, *Applying the Bradford-Hill Criteria in the 21st Century: How Data Integration Has Changed Causal Inference in Molecular Epidemiology*, 2015 EMERG. THEMES EPIDEMIOL. 12:14 ("Temporality is perhaps the only criterion which epidemiologists universally agree is essential to causal inference."), available at https://dx.doi.org/10.1186%2Fs12982-015-0037-4.

[14] As discussed above, Dr. Bellinger has emphasized throughout his academic work the importance of assessing significant confounders when studying neurodevelopmental outcomes like ADHD.

[15] Braun et al., *Exposures to Environmental Toxicants and Attention Deficit Hyperactivity Disorder in U.S. Children*, 114(2) ENVIRON. H. PERSPECT. 1904 (2006).

confounders can change the studies' conclusions regarding lead and ADHD. *See* Froehlich *et al*., *Association of Tobacco and Lead Exposures with Attention-Deficit/Hyperactivity Disorder*, 124(6) PEDIATRICS 1054 (2009) (when prenatal tobacco exposure was added to their analysis, the authors no longer observed a dose-response relationship between of ADHD and BLLs). This shortcoming is also apparent in Dr. Bellinger's reliance on various studies assessing the relationship between lead and aggression. For example, the authors of the Wright (2008) study acknowledged that there were multiple significant confounders they had not accounted for. Once those socioeconomic factors were considered in later studies, the authors found no association between lead and delinquent behavior. *See* Ex. C, Beck Rep. at 25.

Third, the studies are further limited by inconsistencies in how ADHD and aggression or delinquent behavior were identified, diagnosed, or confirmed. For example, in Braun (2006), none of the subjects had an ADHD diagnosis confirmed by a clinician. Ex. B, Bellinger Dep. at 59:18-23; Ex. C, Beck Rep. at 22. Instead, the study relied on self-reporting, which Dr. Bellinger conceded is a weakness of the study. Ex. B, Bellinger Dep. at 59:18–23; Ex. A, Bellinger Rep. at 8. Further, the Nigg (2008) and (2010) studies involved nonrandom populations consisting of children whose parents responded to mailers, thus exposing the studies to "potential selection bias." EPA ISA at 4-175.

3. Dr. Bellinger overstates the strength of the alleged association between arsenic exposure and neurodevelopmental issues in a manner that is inconsistent with his academic work

Dr. Bellinger opines that in addition to lead, arsenic exposure has impacted Plaintiffs' neurodevelopment. *See* Ex. A, Bellinger Rep. at 13 ("[T]he evidence that is available [regarding arsenic and neurodevelopment] provides clear cause for concern."); *id.* at 16 ("[I]t is more likely than not that children who grew up in La Oroya also experienced exposures to arsenic that were sufficient to directly cause their myriad neurodevelopmental impairments."). But, as with his lead

related opinions, Dr. Bellinger fails to account for any of the confounders he has previously identified as significant in his scientific papers. He also fails to acknowledge the weaknesses in the underlying studies that he himself has discussed in his academic papers as contributing to a lack of clarity in scientists' understanding of the relationship between arsenic exposure and neurodevelopment, including whether a relationship in fact exists.

First, as discussed above, Dr. Bellinger has acknowledged before that "neurodevelopment is a complex outcome that is influenced by many factors other than metal exposure." Ex. D, *Arsenic* at 11–12; Ex. B, Bellinger Dep. at 63:17–19. Specifically, Dr. Bellinger has acknowledged in his published scientific paper that the relevant studies have consistently failed to account for confounders and, thus, "do not permit firm conclusions to be drawn regarding" arsenic's impact on neurodevelopmental outcomes. Ex. D, *Arsenic* at 2; *see also* Ex. B, Bellinger Dep. at 84:4–10. Further, Dr. Bellinger has acknowledged that the alleged association between arsenic and neurodevelopment is unclear because there is no identified phenotype for "arsenic-induced" neurodevelopmental deficits. *See* Ex. D, *Arsenic* at 7; *see also* Ex. B, Bellinger Dep. at 81:18–24. This lack of an identifying phenotype coupled with the failure to rule out alternative causes is particularly problematic here, where Plaintiffs have come forward with no sample results or other evidence that any Plaintiff has been exposed to arsenic.[16]

Dr. Bellinger's causation opinion regarding the alleged association between arsenic and neurodevelopment in this litigation compared to the caveats expressed in his academic work, as well as his failure to account for any of the significant confounders he has raised in his academic work both render Dr. Bellinger's methodology in forming his opinions regarding the neurodevelopmental impacts of arsenic unreliable and inadmissible.

[16] *See* Motion to Exclude Ryer-Powder, filed concurrently herewith; Ex. C, Beck Rep. at 28-29.

B. Dr. Bellinger is not qualified to proffer specific causation opinions and has no reliable methodology to do so

Dr. Bellinger's opinions generally relate to general causation principles. Indeed, Dr. Bellinger acknowledges that reaching a conclusion regarding the specific causation of Plaintiffs' alleged injuries falls outside the scope of his expertise and is better left "to the medical doctors to render an opinion on." Ex. B, Bellinger Dep. at 31:4-25; *see also* Bellinger Rep. at 2. Nonetheless, in his report and his deposition, Dr. Bellinger often veered into specific causation opinions. For example, in his report, Dr. Bellinger asserted that "the [16] individuals in the Discovery Cohort have suffered significant deleterious effects from their childhood exposure to lead, and … ***such exposures have directly caused adverse impacts on their educational prospects, their employability and occupational prospects, and their future health and well-being***." Ex. A, Bellinger Rep. at 16. He additionally testified in his deposition that "it's certainly more likely than not that these individuals were harmed by these very high exposures to lead" and that "those exposures will have lifelong consequences for these plaintiffs." Ex. B, Bellinger Dep. at 33:6-25, 34:21-35:5.

These are clearly specific causation opinions, namely, whether these individual Plaintiffs have suffered specific injuries caused by exposure to lead or arsenic. While "[g]eneral causation is a showing that the drug or chemical is capable of causing the type of harm from which the plaintiff suffers[,] … [s]pecific causation is evidence that the drug or chemical in fact caused the harm from which plaintiff suffers." *Junk*, 628 F.3d at 450; *see also Parmentier v. Novartis Pharms. Corp.*, No. 1:12-cv-45, 2012 WL 2324502, at *1 (E.D. Mo. June 19, 2012). To the extent Dr. Bellinger proffers any specific causation opinions, those opinions must be excluded because he is not qualified to offer them and used unreliable methods to form them.

It is undisputed that Dr. Bellinger is an epidemiologist, not a medical doctor or otherwise

qualified to diagnose health conditions. *See In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 960 (D. Minn. 2009) (holding that epidemiologist was not qualified to offer a specific causation opinion that Viagra caused the plaintiff's vision loss because he was "not a medical doctor" and, thus, "not licensed to diagnose the cause of a patient's vision loss"). Even if his opinions on general causation were reliable and admissible, he would not be qualified to diagnose Plaintiffs with any condition or to opine regarding the cause of those alleged conditions in any individual Plaintiff.

Further, as Dr. Bellinger himself acknowledges, to render a specific causation opinion, an expert must rule out other potential causes of the injury or condition. Ex. B, Bellinger Dep. at 35:21-23. "The reliability of a specific causation opinion requires the proffered expert to consider and rule out other likely causes of the plaintiff's alleged ailment, i.e., to perform a proper differential diagnosis." *Simon v. Select Comfort Retail Corp.*, No. 4:14-CV-1136 JAR, 2016 WL 160643, at *5 (E.D. Mo. Jan. 14, 2016). "A differential etiology rules in plausible causes and then systematically rules out less plausible causes until a most plausible cause emerges." *Kirk v. Schaeffler Group USA, Inc.*, 887 F.3d 376, 392 (8th Cir. 2018). However, "[w]hen an expert's differential analysis fails to rule in exposure to the alleged cause at issue (general causation) ***and*** fails to rule out other possible causes, the specific causation opinion is not sufficiently reliable and should be excluded." *Id*. (citing *Bland v. Verizon Wireless, LLC*, 538 F.3d 893, 897–98 (8th Cir. 2008)) (emphasis in original).

Here, Dr. Bellinger conceded that in forming his opinions, he did not perform a differential diagnosis or look to any other potential causes for Plaintiffs' symptoms. Ex. B, Bellinger Dep. at 35:21–36:3. He has not communicated with any Plaintiff, any Plaintiff's parent, or any Plaintiff's treating physician. *Id*. at 21:22-22:3. Nor has he reviewed any Plaintiff's medical records. *Id.* at 18:17-21. He took no steps to rule out potential alternative causes for Plaintiffs' reported

neurodevelopmental deficits. He also acknowledged that several of Plaintiffs' complaints, including gastrointestinal symptoms and poor growth, are nonspecific symptoms with multiple causes. *Id*. at 37:17-25, 65:18-68:5. Nonetheless, he asserted in his report that these symptoms are "classic signs of lead exposure" and that these symptoms were "more likely than not" caused by their exposures. Ex. A, Bellinger Rep. at 15.

Finally, in expressing a specific causation opinion, Dr. Bellinger simply adopts, without independent consideration, the opinions of Dr. Vega and Dr. Hopkins. When an expert bases his opinion on the unreliable opinions of another expert, his opinion is also unreliable. *See Junk*, 628 F.3d at 449 (finding that an expert's opinion was properly excluded when it relied on the excluded opinion of another expert). Dr. Bellinger conducted no independent work and simply relies entirely on Dr. Vega's conclusions from his neuropsychological and behavioral examination of the Plaintiffs and on Dr. Hopkins' conclusions from her physical examination of the Plaintiffs. Ex. A, Bellinger Rep. at 14–16. As shown in Defendants' Motions to Exclude Dr. Vega's and Dr. Hopkins' Testimony, filed concurrently with this Motion, both Dr. Vega and Dr. Hopkins utilized flawed methodologies when forming their opinions about Plaintiffs' alleged cognitive and physical injuries. Further, as Dr. Bellinger merely repeats Dr. Vega's and Dr. Hopkins' opinions regarding specific causation, his testimony on the matter is improper bolstering and should thus be excluded. *See Bavlsik v. Gen. Motors LLC*, No. 4:13 CV 509 DDN, 2015 WL 4920300, at *2 (E.D. Mo. Aug. 18, 2015) ("Finally, as with all evidence, an expert's testimony's probative value must not be substantially outweighed by a danger of unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."); *In re RFC and RESCAP Liquidating Trust Action*, Case No. 0:13-cv-3451 (SRN/HB), Case No. 16-cv-4070 (SRN/HB), 2020 WL 504661, at *3 (D. Minn. Jan. 31, 2020) ("[E]xpert may not offer opinions

which serve no purpose other than to 'bolster' another expert's opinions.") (internal marks omitted).

Dr. Bellinger is not qualified to diagnose Plaintiffs with any medical condition and has failed to use a reliable methodology to do so. Thus, to the extent Dr. Bellinger purports to express any specific causation opinions, those opinions are inadmissible.

C. Dr. Bellinger's opinions regarding arsenic and cancer risks should be excluded

In his report, Dr. Bellinger offers opinions regarding arsenic and cancer, namely that (1) the arsenic associated cancer risks in La Oroya are higher than what is acceptable and (2) that the International Agency for Research on Cancer ("IARC") considers arsenic to be a carcinogen. Ex. A, Bellinger Rep. at 13. Dr. Bellinger, however, admitted that even though he discusses the potential carcinogenicity of arsenic in his report, he is "not providing any opinion about whether [arsenic] might be … a carcinogen in" this case. Ex. B, Bellinger Dep. at 82:16–23. Thus, he should not be permitted to do so at trial.

But, even putting that aside, as no Plaintiff claims to have cancer or a pre-cancerous condition, any opinions on the possible carcinogenic effects of arsenic are irrelevant. One of the factors courts consider when determining the relevance of an expert's testimony under *Daubert* is "whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *See Lauzon*, 270 F.3d at 687. When a plaintiff has not alleged a particular injury, an expert's causation testimony in relation to that injury is irrelevant. *See, e.g.*, *C.C. v. Suzuki Mfg. of Am. Corp.*, No. 4:16-cv-271, 2018 WL 3861354, at *9 (E.D. Mo. Aug. 14, 2018) (holding that expert's testimony regarding helmet use "is irrelevant because there are no alleged brain injuries"). In his report, Dr. Bellinger discusses the cancer risks allegedly associated with arsenic exposure. Ex. A, Bellinger Rep. at 13. However, no Plaintiff has alleged that they have cancer or a pre-cancerous

condition. As such, to the extent Dr. Bellinger purports to offer any opinion on the carcinogenicity of arsenic, it fails the *Daubert* fit criteria and should be excluded.

Finally, Dr. Bellinger's discussion of arsenic and cancer risks overlaps entirely with and is cumulative of, Dr. Ryer-Powder's discussion of those risks. *See Bavlsik*, 2015 WL 4920300, at *2; *In re RFC and RESCAP Liquidating Trust Action*, 2020 WL 504661, at *3. Dr. Ryer-Powder expresses the very same arsenic-related opinions as contained in Dr. Bellinger's report at page 13. *See* Mot. to Exclude Testimony of Dr. Ryer-Powder. Accordingly, Dr. Bellinger's discussion fails to offer a different perspective on the relationship between arsenic and cancer and, thus, should be excluded as cumulative of and improperly bolstering Dr. Ryer-Powder's proposed testimony.

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court exclude or limit the testimony of Dr. Bellinger.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 15th day of November, 2021, a true and correct copy of the foregoing was filed with the Clerk of the Court through the Court's CM/ECF system, which will affect service on all counsel of record by sending a Notice of Electronic Filing.

/s/ *Geoffrey M. Drake*